a design certification rule is in effect under §52.55 or §52.61, unless:

- (i) A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time the certification was issued, or to assure adequate protection of the public health and safety or the common defense and security; and
- (ii) Special circumstances as defined in 10 CFR 52.7 are present. In addition to the factors listed in §52.7, the Commission shall consider whether the special circumstances which §52.7 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order.
- (5) Except as provided in 10 CFR 2.335, in making the findings required for issuance of a combined license, construction permit, operating license, or manufacturing license, or for any hearing under §52.103, the Commission shall treat as resolved those matters resolved in connection with the issuance or renewal of a design certification rule.
- (b)(1) An applicant or licensee who references a design certification rule may request an exemption from one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of §52.7. In addition to the factors listed in §52.7, the Commission shall consider whether the special circumstances that §52.7 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. The granting of an exemption on request of an applicant is subject to litigation in the same manner as other issues in the operating license or combined license hearing.
- (2) Subject to §50.59 of this chapter, a licensee who references a design certification rule may make departures from the design of the nuclear power facility, without prior Commission approval, unless the proposed departure involves a change to the design as described in the rule certifying the design. The licensee shall maintain records of all departures from the facility and these records must be main-

tained and available for audit until the date of termination of the license.

(c) The Commission will require, before granting a construction permit, combined license, operating license, or manufacturing license which references a design certification rule, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determinations, including the determination that the application is consistent with the certification information. This information may be acquired by appropriate arrangements with the design certification applicant.

### **Subpart C—Combined Licenses**

#### §52.71 Scope of subpart.

This subpart sets out the requirements and procedures applicable to Commission issuance of combined licenses for nuclear power facilities.

#### §52.73 Relationship to other subparts.

- (a) An application for a combined license under this subpart may, but need not, reference a standard design certification, standard design approval, or manufacturing license issued under subparts B, E, or F of this part, respectively, or an early site permit issued under subpart A of this part. In the absence of a demonstration that an entity other than the one originally sponsoring and obtaining a design certification is qualified to supply a design, the Commission will entertain an application for a combined license that references a standard design certification issued under subpart B of this part only if the entity that sponsored and obtained the certification supplies the design for the applicant's use.
- (b) The Commission will require, before granting a combined license that references a standard design certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determinations, including the determination that the application

#### § 52.75

is consistent with the certification information.

#### § 52.75 Filing of applications.

- (a) Any person except one excluded by §50.38 of this chapter may file an application for a combined license for a nuclear power facility with the Director, Office of New Reactors or Director, Office of Nuclear Reactor Regulation, as appropriate.
- (b) The application must comply with the applicable filing requirements of §§ 52.3 and 50.30 of this chapter.
- (c) The fees associated with the filing and review of the application are set forth in 10 CFR part 170.

[72 FR 49517, Aug. 28, 2007, as amended at 73 FR 5724, Jan. 31, 2008]

## § 52.77 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33.

# § 52.79 Contents of applications; technical information in final safety analysis report.

- (a) The application must contain a final safety analysis report that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components of the facility as a whole. The final safety analysis report shall include the following information, at a level of information sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a combined license:
  - (1)(i) The boundaries of the site;
- (ii) The proposed general location of each facility on the site;
- (iii) The seismic, meteorological, hydrologic, and geologic characteristics of the proposed site with appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area and with sufficient margin for the limited accuracy, quantity, and time in which the historical data have been accumulated:
- (iv) The location and description of any nearby industrial, military, or transportation facilities and routes;

- (v) The existing and projected future population profile of the area surrounding the site;
- (vi) A description and safety assessment of the site on which the facility is to be located. The assessment must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified paragraphs (a)(1)(vi)(A)in (a)(1)(vi)(B) of this section. In performing this assessment, an applicant shall assume a fission product release<sup>5</sup> from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:
- (A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem<sup>6</sup> total effective dose equivalent (TEDE).

<sup>&</sup>lt;sup>5</sup>The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

<sup>&</sup>lt;sup>6</sup>A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set